



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0891]

Post-Approval Studies 2012 Workshop: Design, Methodology, and Role in Evidence Appraisal Throughout the Total Product Life Cycle; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

Summary: The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Post-Approval Studies 2012 Workshop: Design, Methodology, and Role in Evidence Appraisal Throughout the Total Product Life Cycle.” The topics of discussion will include lessons learned from previous experiences with post-approval studies, improvement of implementation strategies for post-approval studies, best practices, and innovative methodologies for evidence appraisal.

Date and Time: The public workshop will be held on August 30, 2012, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm> .

Contact Persons: Nilsa Loyo-Berrios, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3214, Silver Spring, MD 20993, 301-796-8528, email: [Nilsa Loyo-Berrios @fda.hhs.gov](mailto:Nilsa.Loyo-Berrios@fda.hhs.gov) or Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4110, Silver Spring, MD 20993, 301-796-6689, email: Danica.Marinac-Dabic@fda.hhs.gov.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. on August 23, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. Onsite registration will not be available on the day of the public workshop.

If you need special accommodations due to a disability, please contact Cindy Garris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 66, rm. 4321, Silver Spring, MD 20993, 301-796-5861, email: Cynthia.garris@fda.hhs.gov.

To register for the public workshop, please visit FDA's Medical Devices News & Events-Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Nilsa Loyo-Berrios to register (see Contact Persons). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. on August 28, 2012. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Web cast participants will be sent technical system requirements after registration and will be sent connection access information after August 23, 2012. If you have never attended a Connect Pro event before, test your connection at

https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Comments: FDA is holding this public workshop to provide an update and obtain stakeholders input on post-approval studies ordered at the time of device approval. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is September 30, 2012.

Regardless of attendance at the public workshop, interested persons may submit either written comments regarding this document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of

Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Post-approval studies (PAS) are imposed as conditions of approval for some class III devices regulated under premarket approval (PMA) regulations and are an important public health tool for developing additional evidence on device performance in the postmarket setting. In order for PAS to be most effective, studies must be well-designed, scientifically sound, meaningful and feasible, and must provide complete and timely information. PMA conditions of approval studies are constructed to ask for specific, detailed data in a subsequent PAS relating to unanswered questions in premarket data. However, there are often opportunities for leveraging the design and conduct of PAS, enhancing its utility to other important stakeholders. In addition to the direct role of PMA holders, the role of other public health partners is expanding, as evidenced by a number of efforts external to CDRH that are directly or indirectly involved in

collecting and analyzing data relevant to estimating medical device use and risk and in communicating risk to target populations. To ensure a successful PAS program, CDRH, regulated industry, clinical researchers, and other stakeholders must remain well-informed and engaged in continuous dialogue regarding the design, implementation, reporting, and use of PAS and the resultant data. Further, it is the Center's desire to ensure this dialogue results in studies that maximize the public health impact by producing data that is informative to a range of stakeholders.

II. Topics for Discussion at the Public Workshop

We intend to discuss a large number of issues at the workshop, including, but not limited to the following: (1) PAS within the Total Product Life Cycle, (2) best practices and improvement of PAS implementation strategies, (3) PAS impact on public health and medical device innovation, and (4) opportunities for innovative uses of PAS data.

Dated: August 15, 2012.

Leslie Kux,

Assistant Commissioner for Policy.